

REMARKS

As a result of this present response, claims 34-37, 45-49, 54-57 and 64-66 are in the case. Claims 38-44, 50-53 and 58-63 are withdrawn. This present amendment places the case in condition for allowance and entry of same is respectfully requested.

Information Disclosure Statement

It was noted in the Office Action that the Information Disclosure Statement filed on 3/27/03 was said to fail to comply with 37 C.F.R. 198(a)(2) which required a legible copy of each cited foreign patent document. In that regard, an abstract of the cited documents was filed in an IDS on September 7, 2005. In this present submission, full document copies are presented in a Supplemental IDS, as just received by the undersigned on May 16, 2006. Thus, entry of same is in order, particularly as they correspond directly to the previously submitted abstracts.

Claim Objection

There is an objection to claims 54-57 with regard to depending on claim 1. Appropriate correction has been made in claims 54-57 which now depend directly or indirectly on claim 34.

Rejection of Claims under 35 U.S.C. § 112

Claims 34-37, 45-46, 54-57 and 64-66 were rejected under 35 U.S.C. § 112 first paragraph for failing to comply with written description requirement.

Applicants do not acquiesce to the correctness of this rejection on the basis set forth in the Office Action. The teachings of the present invention are read too narrowly. However, for the purpose of further enhancing clarity for issuance of claims to allowable subject matter, claim 34 presented herewith recites as follows:

A purified and isolated peptide, pE2, consisting of an amino acid sequence identified by SEQ ID NO: 2, or homodimers thereof.

On this basis, it is respectfully submitted that the specification fully supports the invention as defined in claim 34. For this same reason, claims 35-37, 45-49, 54-57 and 64-65 which depend directly or indirectly on claim 34, are also respectfully submitted to meet all of the requirements of 35 U.S.C. § 112 and this rejection should be withdrawn. Note that claim 66 was recited in error in this 112 Office Action rejection and the rejection did not apply to claim 66.

Rejection of Claims under 35 U.S.C. § 102/103 on the Basis of Reyes 5,686,239

Claims 34-37, 45, 47, 54-57 and 64-66 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Reyes et al. (US Patent No. 5,686,239A).

The main claim, claim 34, now defines an anti-HEV reactive pE2 homodimer and unique, new and non-obvious features. The objected-to-language pertaining to derivatives and extensions and the like have been omitted.

Reyes does not teach or suggest the features defined by claim 34. Thus, it is respectfully requested that the rejection on the basis of Reyes under 102/103 be withdrawn.

For the reasons given with respect to claim 34, claims 35-37, and claims 45, 54-57 and 64-65 which depend directly or indirectly on claim 34 are patentable over Reyes.

Note that this rejection does not apply to independent claim 66.

Rejection of Claims under 35 U.S.C. 102 on the Basis of Reyes 5,741,490 (B) or Reyes 5,770,689 (C).

Claims 34-37, 45 and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Reyes et al. (B) (US patent No. 5,741,490A) or Reyes et al. (C) (US Patent No. 5,770,689).

Claim 34 was rejected on the basis that both Reyes et al. (B) and (C) teach an immunogenic composition comprising a HEV antigen polypeptide of HEV ORF2 or C-terminal peptide from HEV ORF2, wherein the polypeptide is SEQ ID NO: 13, 15 or 17, and each of them comprises a fragment that has 100% identity to the claimed pE2 antigen.

Claim 34 as recited above defines pE2, or homodimers thereof that differ from HEV antigen of SEQ ID NO: 13, 15 or 17. Thus, it is not anticipated by said US patents.

Reyes (B) or (C) do not teach or suggest the features defined by claim 34. Thus, it is respectfully requested that the rejection on the basis of Reyes under 102 be withdrawn.

For the reasons given with respect to claim 34, claims 35-37, claims 45 and 47-49 which depend directly or indirectly on claim 34 are patentable over Reyes (B) and (C).

Rejection of Claims under 35 U.S.C. § 102 on the Basis of Khudyakov

Claims 34, 37 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Khudyakov et al. (Virol. 1994, pp. 390-393).

Claim 34 was rejected on the basis that Khudyakov et al. disclose several peptide antigens that are all fragments with 100% identical to the amino acid sequence fragment of SEQ ID NO: 2 (See Table 1). All of these peptides except two (No. 30 and No. 38) are antigen determinants.

Claim 34 defines pE2, or homodimers thereof, differs from HEV peptide antigen of SEQ ID NO: 2. Thus, it is not anticipated by said document.

Khudyakov et al. does not teach or suggest the features of claim 34. Thus, it is respectfully requested that the rejection on the basis of Khudyakov under 102 be withdrawn.

For the reasons given above with respect to claim 34, claims 37 and 64 are patentable over Khudyakov.

Rejection of Claims Under 35 U.S.C. § 102 on the basis of Li et al. U.S. Patent No. 6,514,690B1

Claims 34-37, 45-49, 54-57 and 64-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (US Patent No. 6,514,690B1).

Claim 34 was rejected on the basis that Li et al. disclose a peptide antigen of SEQ ID NO: 18 that comprises a fragment with 100% homology to the claimed peptide E2, wherein the peptide antigen is produced as a glutathione-transferase fusion protein.

Claim 34 defines pE2, or homodimers thereof and the peptide to be protected therein differs from HEV peptide antigen of SEQ ID NO: 18. Thus, it is not anticipated by Li et al.

Li et al. does not teach or support the features of claim 34. Thus, it is respectfully requested that the rejection on the basis of Li et al. under 102 be withdrawn.

For the reasons given with respect to claim 34, claims 35-37, 45-49, 54-57 and 64-65 are patentable over Li et al.

The rejection of claim 66 is in error and claim 66 is patentable over Li.

Allowable Claim 66

Original claims 24 and 25 were said to be allowable except for dependence on claim 22. Claim 66 presented previously is an independent claim which contains the features of respective claims 24 and 25 in the alternative and also contains the features of claim 22. Any prior claim rejections under 35 U.S.C. § 112 have been addressed in claim 66 so as to further enhance clarity. There are no art rejections pertinent to claim 66.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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